REMARKS

FORMAL MATTERS:

Claims 1-7, 9-25, 27-34, 36, 37 and 55 are pending after entry of the amendments set forth herein.

Claim 26 has been canceled without prejudice.

Claim 20 has been amended to incorporate the element of claim 26. Accordingly, no new matter has been added by way of this amendment and entry thereof is respectfully requested.

REJECTIONS UNDER §102

Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36 and 55 were rejected under 35 U.S.C.§ 102(b) as allegedly being anticipated by Bellhouse et al. (USPN 5,630,796; "Bellhouse").

According to the M.P.E.P., a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Additionally, the identical invention must be shown in as complete detail as is contained in the claim. See M.P.E.P. § 2131.

As stated above, Claim 20 has been amended. Claim 20 is directed to a needleless injection device. The needless injection device includes a driver chamber that is arranged to contain a charge of pressurized gas. Further, the needless injection device includes a duct section, which includes a tube of substantially constant cross-sectional area, wherein the duct section is connected to the driver chamber so as to receive gas from the driver. Further still, the needless injection device includes a closure means for preventing the flow of gas from the driver chamber to the duct section until the closure means is opened; and a dose of particles positioned within the device in the region of the closure means.

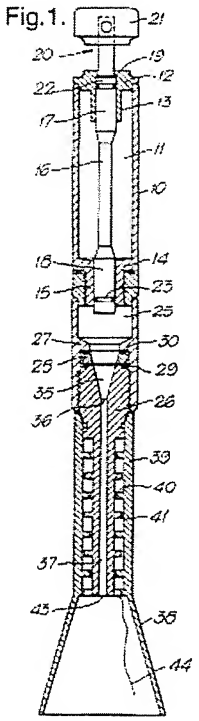
Additionally, the needless injection device is constructed and arranged so that upon opening of the closure means, a primary shock wave is produced and travels along the duct section in a downstream direction and a substantially quasi-steady gas flow is established in the duct section upstream of the primary shock wave. In this manner, a dose of particles is substantially wholly entrained in the

substantially quasi-steady flow, accelerated and expelled from the device.

Accordingly, an element of Claim 20, as amended is a duct section which includes a tube of substantially constant cross-sectional area. This duct section functions, in conjunction with the other elements of the claimed device, to produce a primary shock wave that travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave. Hence, given the structure of the claimed device, upon operation, a dose of particles will substantially be wholly entrained in the substantially quasi-steady flow, accelerated and expelled from the device.

In maintaining this rejection the Office asserts that Bellhouse discloses the needleless injection device of Fig. 1, below. The Office asserts that the device includes a rupturing membrane closure means (34), substantially constant diameter driver chamber (25), substantially constant diameter duct section (37) connected to the driver chamber (25) to receive gas therefrom, a dose of particles upstream of the closure means (34), divergently contoured nozzle (38) downstream of the duct (37) through which a flow travels, whereby the device generates a shock wave upon rupturing of the membrane.

Fig.1.



In view of Fig. 1 above, it appears that the Office is equating the "divergent part" (37), as disclosed by Bellhouse, with the "duct section," as claimed by the Applicants. However, the "duct section," as claimed by the Applicants, includes a tube of substantially constant cross-sectional area. It is clear from column 12, line 45 of Bellhouse, that the "divergent part" (37) is not substantially constant in cross-sectional area. Rather, "divergent part" (37) is a divergent section of a convergent nozzle (38). The "convergent part" is set forth as element (35). See below.

> The passageway through the nozzle **26** has an upper convergent (in the downward direction of flow) part **35** leading through a throat **36** to a divergent part **37**. The

Accordingly, the element (38), referred to by the Office as a "divergently contoured nozzle," is in fact a divergent spacer shroud. See, for instance, column 12, line 49, below. The purpose of the spacer shroud 38 is merely to space the end of the divergent nozzle 37 from the target. The spacer shroud 38 does not influence the flow of gas in a significant manner because it is offset from the gas flow.

> internal shape of the ring **31**. The nozzle is surrounded by a tubular portion providing a divergent spacer shroud **38** and a cylindrical silencer part **39** made in two halves divided by a longitudinal diametral plane. The upper ends of these two

Hence, as can be seen with reference to the above, the Bellhouse device does not include a duct section which includes a tube of substantially constant cross-sectional area, as recited in the Applicants amended claims.

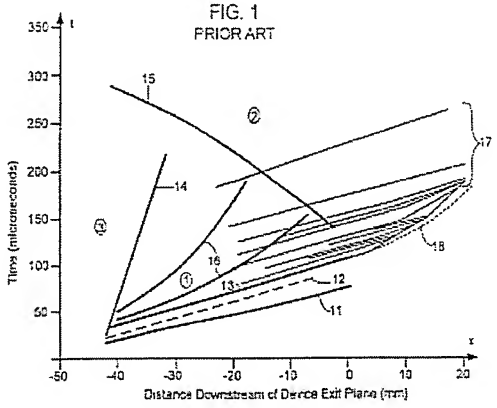
Further, given this structural difference, the Bellhouse device is not constructed and arranged so that upon opening of the closure means, a primary shock wave is produced that travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave.

For instance, the Bellhouse device operates as follows. The plunger (21) is depressed and gas from reservoir (10) flows under pressure into the chamber (25). When the bursting pressure of the diaphragm (33) is reached, this diaphragm bursts and, very shortly thereafter, the diaphragm (34) bursts.

The gas, containing the particles, thereafter flows through the convergent section (35) and divergent section (37) where it is accelerated to high speeds.

However, as explained in the Applicants response of May 30, 2006, the fact that the gas containing the particles in this area is accelerated to high speeds does not mean that a quasi-steady flow is established. Rather, when gas flows through the convergent (35) or divergent section (37), shockwaves and expansion waves result. Such waves are transient and form part of a "starting process". This starting process in the Bellhouse device is described in the Applicants' specification from page 2, line 27 to page 3, and with relation to Figure 1, below.

FIG. 1
PRIOR ART



It can be seen from Figure 1 that the particle trajectories (17) pass through the shockwaves (13) and (16) as well as shock front (15) that moves upstream from the nozzle exit.

Thus, as disclosed in Bellhouse, the fact that the particles are driven by gas into a convergent section (35) through a throat (36) and then into a divergent section (37) means that the position of the starting process coincides with the position of the particles in the gas flow. This is made explicitly clear in Bellhouse at column 5, lines 57 to 61, below.

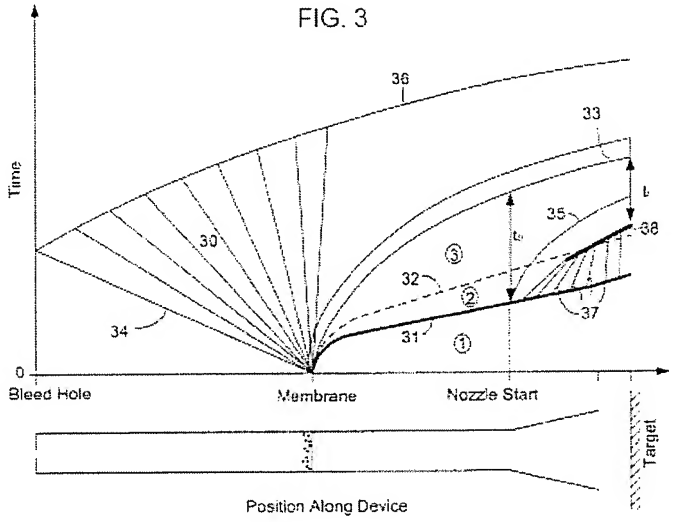
It has now been appreciated that there is another advantage in using helium for bursting the membrane. It is believed that most of the particles travel on or behind the contact surface between the upstream and downstream gases which are initially separated by the membrane, the contact surface closely following the shockwave. It appears that the

As can be seen with respect to the cited passage, most of the particles travel on or behind the contact surface, between the upstream and downstream gasses which are initially separated by the membrane, closely following the shockwave. This understanding is confirmed by the experimental evidence shown in Figure 1, above, wherein the particle trajectories (17) are shown closely following the contact surface (12).

It will, therefore, be appreciated that, due to the convergent/divergent nozzle elements (35), (36), and (37) and their proximity to the membrane (34), where the particles are located, that the starting process (which involves the production of transient shock and expansion waves) coincides with the acceleration of the particles. Thus, the particles are not accelerated in the quasi-steady flow which follows the starting process.

This is contrasted with the embodiment of the Applicants' invention shown in Figure 3, wherein a substantially constant cross-sectional area duct section is shown as being connected to the driver chamber downstream of the membrane.

FIG. 3



Thus, when the membrane bursts, the shockwave moves forward along the constant diameter driving section and creates a starting process only at the point where the duct section meets the nozzle. At this point, the starting process is characterized by the shockwave (38) and expansion wave (37) shown in Figure 3, above.

Due to the fact that this process is initiated at some point downstream of the membrane, the whole process is swept out of the nozzle by the time that the particles (33) arrive. The particles (33) are, therefore, wholly entrained within the quasi-steady flow that follows the starting process. This is achieved in part by way of the structural feature of a substantially constant cross-sectional area duct section.

It is simply not possible to accelerate particles in a quasi-steady flow using the device of Bellhouse. The convergent/divergent nozzle and its proximity to the membrane 34, with no constant area duct section in between, means that the particles will get caught up in the starting process. This fact is experimentally confirmed by Figure 1 of the present application.

Hence, contrary to the assertions of the Office, the Bellhouse device does not *inherently* possess the claimed elements; the evidence of Figure 1 cannot simply be dismissed. Further, simply because Bellhouse discloses that the particles are *entrained in a supersonic gas flow* does not mean that the particles are *entrained in a quasi-steady flow*, as claimed. Accordingly, as described above, a gas flow having transient shockwaves, due to a given starting process, may be supersonic without being quasi-steady. It is, therefore, erroneous to equate the term "supersonic gas flow" with "quasi-steady gas flow".

Additionally, the Office requests that the Applicants provide data showing that Bellhouse cannot perform in the same manner as the Applicants' claimed device. In response, the Applicants kindly direct the attention of the Office to the above, specifically the data presented in relation to Figures 1 and 3.

Conclusion as to the rejections under 35 U.C.S.§102(b)

In view of the above, Claim 20, and the claims dependent thereon, includes structural elements (e.g., a substantially constant duct section), not disclosed in Bellhouse, that function to allow the claimed entrainment in the quasi-steady flow to take place. Rather, the Bellhouse device discloses that the particles travel with the contact surface, which will always be caught up in the starting process, and will not be wholly entrained in the substantially quasi-steady flow. Therefore, the Applicants contend that Bellhouse does not anticipate the rejected claims because Bellhouse fails to teach all the elements of the claimed invention.

Consequently, the Applicants respectfully request that the 35 U.S.C. §102(b) rejection of Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36 and 55 be withdrawn.

REJECTIONS UNDER §103(a)

Claims 1-7, 9-18, 20-34, 36 and 55 are rejected under 35 U.S.C.§103 (a) as allegedly being unpatentable over Heinzen (WO 97/47730) in view of Bellhouse et al. (USPN 5,899,880; "Bellhouse").

According to the M.P.E.P. § 706.02 (j), to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Office asserts that Heinzen discloses a needleless injection device that includes a rupturing membrane closure means 18, diameter driver chamber 13, a duct section 22, dose of particles in region of closure means 14, divergently contoured nozzle 24 through which a flow travels, whereby the device generates an accelerated gas stream upon rupturing the membrane. The Office acknowledges that establishing a quasi-steady flow upstream of a shock wave as well as entraining and accelerating particles in the quasi-steady flow is not taught by Heinzen. The Office, however, concludes that because Heinzen allegedly discloses all the structural elements recited in the Applicants' rejected claims that the operation of the Heinzen device will necessarily result in the establishment of a quasi-steady flow upstream of a shock wave as well as the entrainment of the accelerated particles within the quasi-steady flow.

The Applicants respectfully disagree and contend that the reasoning of the Office is erroneous. Simply because one device may have all the structural elements as another device does not necessarily mean that the devices will function in the same manner. Rather, it is how those structural elements are configured and how they interact with one another that determines the functioning of the over all device. Accordingly, the Applicants contend that the Heinzen device does not function in the same manner as

the device of claim 20 because the Heinzen device is not configured in the same manner as that of the Applicants' claimed device.

Specifically, as set forth in the Applicants' response filed May 30, 2006, the carrier particles (16) of the Heinzen device are forward (i.e., downstream) of the tubing element (13; which the Office equates with the Applicants' claimed driver chamber) and membrane (18). Hence, when the membrane (18) is ruptured the particles (16) will be downstream of (e.g., in front of) the primary shock wave. Because the particles will be in front of the primary shock wave the flow produced will be different from that produced by the device claimed by the Applicants. Therefore, the Heinzen device does not necessarily produce a primary shock wave that travels along the duct section (52) in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section, upstream of the primary shock wave, wherein the particles are wholly entrained within the quasi-steady flow.

Further, to the extent that the Office relies upon Bellhouse to remedy the deficiencies of Heinzen, the Applicants refer the Office to the above wherein is described that Bellhouse is deficient in that it fails to teach a device that is configured so that upon opening of a closure means, a primary shock wave is produced and travels along a duct section in a downstream direction in a manner sufficient to both establish a substantially quasi-steady gas flow, in the duct section upstream of the primary shock wave, and to substantially wholly entrain a dose of particles in the substantially quasi-steady flow. As the Heinzen device is deficient in the same regards, Bellhouse cannot be relied upon to remedy the deficiencies of Heinzen.

Accordingly, neither the Heinzen nor the Bellhouse device functions to allow the claimed entrainment of particles within a quasi-steady flow. Therefore, the Applicants contend that neither Heinzen nor Bellhouse, either alone or in combination, teach or suggest all the elements of the rejected claims. Consequently, a *prima facie* case of obviousness has not been established and the Applicants respectfully request that the 35 U.S.C. §103(a) rejection of Claims 1-7, 9-18, 20-34, 36 and 55 be withdrawn.

Claims 19 and 37 were rejected under 35 U.S.C.§103 (a) as allegedly being unpatentable over Heinzen (WO 97/47730) in view of Bellhouse et al. (USPN 5,899,880; "Bellhouse") in further in view of Bellhouse '478.

Both of claims 19 and 37 ultimately depend from claim 20. As set forth above, the device of claim 20, as amended, includes a substantially constant duct section that functions in conjunction with the other claimed elements of the device to produce a primary shock wave which travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave.

As set forth above, the combination of Heinzen in view of Bellhouse '880 is deficient in that it fails to teach all the elements of the Applicants' claims. As Bellhouse '478 was cited for its disclosure of scoring a rupturable membrane and selecting different gases to give different velocities it fails to remedy the deficiencies of Heinzen in combination with Bellhouse '880.

In light of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Heinzen in view of Bellhouse '880 and further in view of Bellhouse '478 fails to teach all the elements of the Applicants' claims.

Conclusion as to the rejections under 35 U.C.S. §103 (b)

The Applicants submit that the rejection of claims 1-7, 9-18, 19, 20-34, 36, 37 and 55 under 35 U.S.C.§103 (b) as allegedly being obvious over Heinzen in view of Bellhouse '880 and further in view of Bellhouse '478 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number KEMP-002.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 12·21·06

By: _____
James S. Nolan
Registration No. 53,393

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231